



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

94804d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: FEI 3004511730

June 21, 2004

Mitsuo Fujimoto, President  
Ocean Queen USA, Inc.  
330 Shaw Road  
South San Francisco, California 94080

**WARNING LETTER**

Dear Mr. Fujimoto:

On April 7, 8, 13, and 19, 2004, the United States Food and Drug Administration (FDA) inspected your seafood processing facility located at 330 Shaw Road, South San Francisco, California. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fish and fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated histamine forming fish, e.g., tuna and yellowtail (Hamachi), and your refrigerated ready-to-eat fish and fishery products, e.g., salmon are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the FDA's Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001 through links in FDA's home page at [www.fda.gov](http://www.fda.gov). We listed the deviations on a Form FDA-483 and discussed them with you at the conclusion of the inspection. Your serious deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must

have a written HACCP plan to control any food safety hazards that are likely to occur, to comply with 21 CFR 123.6(a) and (b). However,

- a) Your firm does not have a HACCP plan for fresh chilled tuna to control histamine formation and also to control pathogen growth and toxin formation (for tuna intended for raw consumption) as a result of time/temperature abuse during the receipt and storage of the product;
  - b) Your firm does not have a HACCP plan for fresh, chilled, vacuum packaged Yellowtail (Hamachi) to control histamine formation and Clostridium botulinum growth and toxin formation as a result of time/temperature abuse during the receipt, storage, and distribution of the product; and
  - c) Your firm does not have a HACCP plan for fresh, chilled ready-to-eat salmon to control pathogen growth and toxin formation as a result of time/temperature abuse during the receipt and storage of the product.
2. You must monitor and maintain records of sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b) and (c). However, you firm is not monitoring and keeping records of monitoring to ensure control of the eight key sanitation areas.

You must immediately take appropriate steps to correct the violations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the violations. You may wish to include in your response documentation such as copies of your HACCP plan, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practices (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

*C D Moss Acting DD*

*for*

Barbara J. Cassens  
District Director  
San Francisco District